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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,588	12/04/2001	Hiroyuki Miura	2224-0194P	6379
2292	7590	03/19/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			ANDERSON, REBECCA L	
			ART UNIT	PAPER NUMBER

1626

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,588	Applicant(s) MIURA ET AL.	
	Examiner Rebecca L Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>213</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3 and 18 are currently pending in the instant application and are rejected as follows.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 08 December 2003 and 18 February 2004 have been entered.

Response to Amendment

Applicant's arguments and amendments filed 8 December 2003 and 18 February 2004 have been fully considered but they are not persuasive.

Applicant's amendment to the claims filed 08 December 2003 which amended claim 1 to include the proviso "that said substrate is not an isoprenoid which has at least one allylic hydrogen atom" has been amended in a preliminary amendment filed 18 February 2004 to change the proviso to "that said substrate is not a terpene. Minor formal amendments were made to claims 2 and 3.

Applicant argues that in order to clarify the difference between the present invention and Foricher, claim 1 has been amended to "exclude terpenes (including the isoprenoid compounds of Foricher) from the substrate" (Page 4 of the remarks filed 18

February 2003). However, this argument is not found persuasive because according to Foricher, column 2, lines 66-68,

"Accordingly, isoprenoids include the compounds described in greater detail under specific entries, namely heriterpenes, terpenes,"

Therefore, the term "terpenes" does not include the isoprenoid, the term "isoprenoid" includes terpenes and therefore, the Foricher reference still anticipates applicants invention since it discloses the process of oxidizing an isoprenoid having at least one allylic hydrogen atom in the presence of a N-hydroxydicarboxylic acid imide of the formula (I) such as N-hydroxyphthalimide. Furthermore, the oxidation of α -pinene is found on columns 5 and 6 of the Foricher reference and applicants instant specification states on page 26, for the substrates,

"As bridged cyclic hydrocarbons, there may be mentioned, for example, bicyclic hydrocarbons (e.g. pinane, pinene.....) and terpenes...."

Since substrates of the Foricher reference, i.e isoprenoids having at least one allylic hydrogen atom that are other than terpenes, are not excluded, the rejection under 35 U.S.C. 102(b) is maintained because the isoprenoid having at least one allylic hydrogen still falls within applicants claimed substrate as it is an hydrocarbon.

Applicants argument of unexpected benefits is moot since the rejection is under 35 U.S.C. 102(b) as being anticipated by Foricher et al. This argument is not persuasive and is moot because applicant is arguing limitations that are not found in the applicant's instant claims. Specifically, applicants claim language of comprising allows for other steps to be in the process. Also, applicants instantly claimed process comprises two reactions, i.e. a) the reaction of a substrate in the presence of an imide

Art Unit: 1626

compound and then b) subsequently separating said reaction product and said imide compound by solvent-crystallizing the imide compound from said reaction mixture.

Foricher et al. discloses a process which falls within the instantly claimed invention which is the process of oxidizing an isoprenoid with at least one allylic hydrogen atom in the presence of a N-hydroxydicarboxylic acid imide of the formula (I), such as N-Hydroxyphthalimide (NHPI) (Table 1, column 9, lines 42-59). The separation of the catalyst from the reaction mixture is disclosed on column 4, lines 50-62, wherein the catalyst can be separated (crystallized-out) from the reaction mixture with the aid of a non-polar solvent, such as hexane.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 and 18 are drawn to processes for preparing a reaction product. However, the claims are silent as to what the substrate is reacted with in the presence of the catalyst. Since the specification is also silent as to what compounds are encompassed by the phrase "reaction product" which is found in claim 1, claims 1-3 and 18 are considered indefinite because it is unclear what compounds are being produced in the process and it is impossible to determine what compounds are encompassed by the phrase "reaction products".

Claims 1-3 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step of reacting the substrate with another reactant or reagent, such as an oxidizing agent, for example atmospheric oxygen. The instant claim fails to include what the substrate is reacted with in the presence of the imide catalyst to produce the reaction product. The exclusion of what the substrate is reacted with is critical and essential to the process claimed since it is required to determine the process and the reaction product.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of oxidation products of oxidation reactions of hydrocarbons, alcohols, aldehydes, ketones, amines, heterocyclic compounds, thiols, sulfides and amides, does not reasonably provide enablement for production of any reaction product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case,

The nature of the invention

The nature of the invention is the process for preparing a reaction product from an oxidation reaction of a substrate selected from the group consisting of a hydrocarbon, an alcohol, an aldehyde, a ketone, an amine, a heterocyclic compound, a thiol, a sulfide and an amide (excluding terpenes) in the presence of an imide compound and separating the reaction product from the imide compound by solvent-crystallizing the imide compound from the reaction mixture with a hydrocarbon, a chain ether or water.

The state of the prior art

The state of the prior art is that the catalytic oxidation of an isoprenoid containing at least one allylic hydrogen atom with oxygen or an oxygen containing gas in an inert solvent in the presence of an imide catalyst will produce a primary or secondary hydroperoxide (see Foricher et al.)

The predictability or lack thereof in the art

The predictability or lack thereof in the art is that the oxidation of a substrate will result in a loss of electron density by carbon by forming, for example, a C-O bond or breaking a C-H bond

The amount of direction or guidance present and the presence or absence of working examples

The amount of direction or guidance present in the instant specification is the reaction of the above mentioned substrates with atmospheric oxygen to produce oxidation reaction products as can be seen in the examples beginning on page 96 of the instant specification.

The breadth of the claims

The breadth of the claims is the process of reacting a substrate to produce any type of reaction product.

The quantity of experimentation needed and the level of the skill in the art

The quantity of experimentation to produce any reaction product from the above mentioned substrates is undue. One would have to determine what reaction conditions, reactants and reagents are required to react with each substrate in order to produce any reaction product with only direction given in the specification for the preparation of oxidation reactions of the substrates to produce oxidation reaction products. While the level of skill in the art is high, the lack of support in the instant specification and claims to produce any reaction product from the substrates in claim 1 necessitates the requirement of undue experimentation to determine what reaction conditions, reactants, reagents would be needed to produce any reaction product from the substrates in the presence of the imide catalyst. This rejection could be overcome, for example, by

Art Unit: 1626

including what the substrate is reacted with and limiting the reaction products to only oxidation reaction products that can be formed from the instant substrates.

Maintained Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Foricher et al. as found in the office actions mailed 19 March 2003 and 8 September 8 2003 is maintained for essentially those reasons as found in the prior office action and below:

The instant application claims a process for preparing a reaction product which comprises the steps of reacting a substrate selected from the group consisting of a hydrocarbon, an alcohol, an aldehyde, a ketone, an amine, a heterocyclic compound, a thiol, a sulfide, and an amide, with the proviso that said substrate is not a terpene, in the presence of an imide compound having an imide unit represented by formula (1) thereby forming a reaction mixture, and subsequently separating said reaction product and said imide compound from said reaction mixture by solvent-crystallizing the imide compound from said reaction mixture with at least one solvent selected from the group consisting of a hydrocarbon, a chain ether and water (claim 1). Claim 2 claims the process of claim 1 wherein the hydrocarbon of the solvent-crystallization step is an aliphatic hydrocarbon having 4 to 16 carbon atoms or an alicyclic hydrocarbon having 4 to 16 carbon atoms, and the chain ether is a diC1-6alkyl ether or a C1-6alkyl C6-10aryl ether. Claim 3 claims the process of claim 2 wherein the imide compound is an aromatic imide compound, and the reaction product is an oxidation reaction product of

Art Unit: 1626

an alicyclic hydrocarbon or an alicyclic alcohol and is soluble in the solvent for crystallization in the solvent-crystallization step. Claim 18 claims the process of claim 1 wherein the imide compound is an oxidation catalyst for oxidizing the substrate and the reaction product is an oxidation reaction product corresponding to the substrate.

This invention was described in the prior art US Patent No. 5, 030, 739 more than one year prior to the date of the instant application. US Patent No. 5, 030, 739 discloses the process of oxidizing an isoprenoid having at least one allylic hydrogen atom(column 1, lines 39-59), such as terpenes, sesquiterpenes and steroids (column 2, lines 43-57), such as α -pinene (column 3, lines 28-36) in an inert ketone or ester in the presence of a N-hydroxydicarboxylic acid imide of the formula (I), such as N-Hydroxyphthalimide (NHPI) (Table 1, column 9, lines 42-59). The separation of the catalyst from the reaction mixture is disclosed on column 4, lines 50-62, wherein the catalyst can be separated (crystallized-out) from the reaction mixture with the aid of a non-polar solvent, such as hexane. An example of the oxidation of α -pinene is found in example b), columns 5 and 6 the imide compound used was NHPI (see experiment (b) in Table 1). Another example of the oxidation of α -pinene is found in example 4, columns 9-10, wherein α -pinene is reacted with NHPI and the imide is separated out with hexane/diethyl ether, (i.e. the substrate α -pinene, an alicyclic hydrocarbon which is soluble in the hexane/diethyl ether solution (as seen by the filtrate being evaporated to dryness and the resulting residue containing the final oxidation product), is oxidized with the aromatic oxidation catalyst NHPI and then the catalyst is separated out by a solvent crystallization step with the aid of a solvent mixture of hexane, an alicyclic hydrocarbon

Art Unit: 1626

having 6 carbon atoms, and diethyl ether, a diC1-6alkyl ether). The prior art substrate is an isoprenoid having at least one allylic hydrogen atom, such as α -pinene which corresponds to applicants claimed substrate of a hydrocarbon and is not within the proviso because the term "terpene", which is provided out, is instead, within the isoprenoid having one allylic hydrogen atom. This rejection could be overcome, for example, by deleting the substrates "hydrocarbon, alcohols, aldehydes and ketones" from the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier number for accessing the facsimile machine is (703) 872-9306



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